



CERTIFICATE OF ANALYSIS

Name of the Product	:	Diafiltration buffer pH-4.0 solution	Part No.	:	SS/33
Batch No.	:	SS/33/0001	Batch Size	:	400 Lit.
Retest Date	:	1 Year from the date of manufacturing			
AR No.	:	AR/SS/33/0001			
Packing Details	:	Buffer solution packed in aseptic bag as primary packaging material and LDPE totes as secondary packaging material.			

Sr. No.	Test Parameters	Specification	Result
1.	Appearance	Clear Colourless solution	Complies
2.	pH of Solution	4.0 ± 0.1	Complies
3.	Conductivity of Solution	$\leq 200 \mu\text{S/cm}$	Complies
4.	Osmolality of Solution	$295 \pm 7 \text{ mOsm/kg}$	Complies
5.	Bioburden	$<100 \text{ CFU/100 mL}$	Complies
6.	Endotoxin	$<1.0 \text{ EU/mL}$	Complies

Remark:

Storage condition of solution is preferred to store at ambient temperature.

Conclusion:

The above product complies / ~~not complies~~ as per above specifications.



Approved By: - _____